

Notice of Allowability	Application No.	Applicant(s)
	10/501,407	VAN BEUSECHEM ET AL.
	Examiner	Art Unit
	SCOTT LONG	1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 4/28/2011.
2. ☒ The allowed claim(s) is/are 10,17,19-23,26-29 and 32-40.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some*c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).**
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. <input type="checkbox"/> Notice of References Cited (PTO-892)	5. <input type="checkbox"/> Notice of Informal Patent Application
2. <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)	6. <input checked="" type="checkbox"/> Interview Summary (PTO-413), Paper No./Mail Date <u>20110224</u> .
3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____	7. <input type="checkbox"/> Examiner's Amendment/Comment
4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material	8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance
	9. <input type="checkbox"/> Other _____.
/SCOTT LONG/ Primary Examiner, Art Unit 1633	

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/28/2011 has been entered.

Priority

This application claims benefit from foreign Application No. EP/02075108.7, filed 14 January 2002 and PCT Application No. PCT/EP03/00340, filed 14 January 2003. The instant application has been granted the benefit date, 14 January 2002, from the application EP/02075108.7.

37 CFR 1.132 Declaration

The examiner acknowledges receipt of the Declaration under 37 CFR 1.132 by Dr. Frank McCormick filed on 28 April 2011.

The Declaration under 37 CFR 1.132 filed 28 April 2011 is sufficient to overcome the rejection of claims 26-35 and 38-40 based upon *obviousness over Curiel et al. in*

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view of Xu et al. and claims 36-37 based upon *obviousness over Curiel et al. in view of Xu et al. and further in view of Lin et al.* as set forth in the last Office action because:

The affiant has set forth the prevailing views of experts in the field of adenoviral gene therapy. The affiant has provided an opinion that the combination of elements provided by Curiel and Xu would not be expected to "replicate and have lytic capacity." The affiant is not one of the instant inventors. Therefore, the examiner gives his opinion due weight appropriate as being from an objective artisan skilled in the field of adenoviral gene therapy. The examiner can find no flaw in the scientific logic of the affiant's opinion.

In assessing the weight to be given expert testimony, the examiner may properly consider, among other things, the nature of the fact sought to be established, the strength of any opposing evidence, the interest of the expert in the outcome of the case, and the presence or absence of factual support for the expert's opinion. See Ex parte Simpson, 61 USPQ2d 1009 (BPAI 2001), Cf. Redac Int'l. Ltd. v. Lotus Development Corp., 81 F.3d 1576, 38 USPQ2d 1665 (Fed. Cir. 1996), Paragon Podiatry Lab., Inc. v. KLM Lab., Inc., 948 F.2d 1182, 25 USPQ2d 1561, (Fed. Cir. 1993).

Upon consideration of the facts taught by the prior art and the information submitted by the Affiant, the balance of evidence indicates that the prior art does not teach the instantly claimed inventions.

RESPONSE TO ARGUMENTS

35 USC § 103

The rejection of claims 26-35 and 38-40 under 35 U.S.C. 103(a) as being unpatentable over Curiel et al (US-6,824,771) in view of Xu et al. (Human Gene Therapy. 1997; 8:177-185) is withdrawn in response to the applicant's arguments and McCormick Declaration.

The rejection of claims 36-37 under 35 U.S.C. 103(a) as being unpatentable over Curiel et al (US-6,824,771) in view of Xu et al. (Human Gene Therapy. 1997; 8:177-185) as applied to claims 26 and 35 above, and further in view of Lin et al. (Cancer Research. Oct 15, 2000. 60. p.5895-5901) is withdrawn in response to the applicant's arguments and McCormick Declaration.

The applicant's arguments have been fully considered and are persuasive. The McCormick Declaration is discussed above in the 37 CFR 1.132 Section. The McCormick Declaration was found sufficient to overcome the art of record.

Therefore, the examiner hereby withdraws all rejections of record.

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview

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with Lauren Emr on 27 June 2011.

The claims have been amended as follows:

10. (Amended) The recombinant virus according to ~~claim 4~~ claim 26, wherein the restoring factor is chosen from the group consisting of p53, p63, p73, BAX, BAK, BOK/Mtd, BCL-Xs, Noxa/APR, PIDD, p53AIP1, ~~PUMA, KILLER/DR5~~ PUMA, KILLER/DR5, Apaf-1, PIG, BID, tBID, BAD, HRK, Bik/Nbk, BLK, mda-7, p14ARF or functional variants, analogues or derivatives thereof.

Claims 15-16 are cancelled.

17. (Amended) The method for lysing target cells hampered in the p53 dependent apoptosis pathway, comprising the steps of: ~~infected~~ infected the said target cells with the replication competent recombinant virus according to ~~claim 4~~ claim 26, and ~~replicating~~ replicating said virus within said target cells, further comprising the step of providing, in the virus genome, the coding sequence of at least one restoring factor functional in restoring the p53 dependent apoptosis pathway, said coding sequence being capable to be expressed in the target cells upon infection thereof by said virus.

21. (Amended) A method for treatment of a subject body suffering from a condition involving body cells hampered in a p53 dependent apoptosis pathway, comprising the step of administering to said subject body an effective amount of the replication competent recombinant adenovirus according to ~~claim 4~~ claim 26.

Reasons for Allowance

The following is an examiner's statement of reasons for allowance:

The prosecution history provides evidence for allowability. In particular, The 37 CFR 1.132 McCormick Declaration (filed 4/28/2011) was found sufficient to overcome the art of record.

As the method claims have been amended to recite all the limitations of the allowable product claims, they have been rejoined.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Claims 10, 17, 19-23, 26-29 and 32-40 are allowed.

Examiner Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Scott Long** whose telephone number is **571-272-9048**.

The examiner can normally be reached on Monday - Friday, 9am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Joseph Woitach** can be reached on **571-272-0739**. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/SCOTT LONG/
Primary Examiner, Art Unit 1633